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Declaration of Prof. Dr. Benno Kunz Under 37 C.F.R. §1.132

Honorable Commissioner for P.O. Box 1450 Alexandria, VA 22313-1450

I, BENNO KUNZ declare and state that:

- 1. I am a resident of the Federal Republic of Germany.
- 2. I am a citizen of the Federal Republic of Germany.
- (equivalent to MS in engineering) from the Technical University of Dresden and a Dr.-Ing degree from the same university in Germany, in 1965-1970, respectively 1970-1973. Since 1989 I have a chair of Food Technology and Food Biotechnology at the University of Bonn, Germany. I'm executive director of the institute of Food Technology of Bonn University and I was dean of the agricultural faculty from 1994 to 1996. At the same time, my institute has been under numerous research agreements with industrial and Institutional partners from various countries.
- 4. I have been giving lectures in biotechnology, food technology, and process engineering since 1975. I'm doing research in the area of microencapsulation. Some of my institute publications in this field are:
 - Chancen und Grenzen der Mikroverkapselung in der modernen Lebensmittelverarbeitung. CIT (75) 9 in press 2003 [Chances and limits of microencapsulation in modern food technology]

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- Influence of Different Capsule Materials on the Physiological Properties of Microencapsulated Lactobacillus acidophilus. Diss. Bonn 2003 in press
- 3.
- 4. Stabilization of Probiotics. Dechema Jahrestagung der Biotechnologen, MtInchen 2003 [DECHEMA annual meeting of biotechnologists]

Since 1998 my institute together with two companies is participating in a project for microencapsulation of bioactive substances. The project is partially funded by the federal Government.

- 5. I consider myself qualified by my knowledge of blotechnology, bloprocess engineering, food technology, and food biotechnology and by my years of experience in these technical fields for more than 20 years.
- I am a co-inventor of the above-captioned United States Patent
 Application and therefore have personal knowledge of its subject matter.
- 7. I have read and understand the Official Action mailed on December 4, 2003 ("the Office Action").
- 8. I understand that claims 1 through 3 and 5 through 10 stand rejected as being unpatentable over United States Patent No. 5,429,832 to Ueda et al. ("Ueda").
- 9. I understand that claims 1, 2, 6, 8 through 10 and 12 through 19 stand rejected as being unpatentable over United States Patent No. 6, 120, 811 to Ghani. ("Ghani") in view of Ueda.

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- 10. The Office Action notes that the term "encapsulated" does not convey any degree of completeness of the coating.
- in contrast to the position urged within the Office Action, the term "encapsulated" is understood by one skilled in the art to mean that an innermost material has been completely surrounded or enveloped by an outer shell material. Stated differently, one skilled in the art understands the term "encapsulated" to refer to structures having an innermost material that is disposed within a continuous outer shell.
- 12. As further evidence that those skilled in the art understand "encapsulated" to mean structures which have materials disposed within a continuous outer shell, the following exerpts by other authorities in the field are provided below:
- "Microencapsulation is a thechnique whereby liquid droplets, particles, or gas bubbles of a "core-material" are entrapped in a continuous film of a polymer the "wall-material". Zilberboim, R., Kopelmann, I. J., Talmon, Y., Microencapsulation by a Dehydrating Liquid: Retention of Paprika Oleoresin and Aromatic Esters, Journal of Food Science 1986, 51 (5), S. 1301-1306:
- "Microencapsulation is defined as a technology of packaging solids, liquids, or gaseous materials in miniature, <u>sealed capsules</u> that can release their contents at controlled rates under specific conditions." Dziezak, J. D., Microencapsulation and Encapsulated Ingredients, Food Technology 1988, 4, S. 138-151.
- 15. "In the course of some twenty years, microencapsulation of small particles in envelopes of protective shell materials has become an established technology for coating and Isolating liquid or solid substances until such time that their activity is needed. "Ré, M. I., Microencapsulation by Spray Drying, Drying Technology 1998, 16, S. 1195-1236.

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- 16. In contrast to the continuous shells of microencapsulated products, the microgranules of Ueda and Ghani are not required to be continuous. In fact, I respectfully submit that the microgranules formed by the agglomeration techniques of Ueda and Ghani would not provide continuous shells for each microgranule. Accordingly, the encapsulated structures of the claimed invention are altogether different from the microgranules of Ueda and Ghandi.
- 17. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and flirther that these statements were made with the knowledge that willml ialse statements and the like so made are punishable by me or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willM false statement may leopardize the validity of the application or any patent Issued thereon.

26-2-04

Date

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